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I, LEANNE MYNOTT, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PP 8915 for a patent by WOLFE RESEARCH PTY LTD filed on 01 March 1999.

WITNESS my hand this
Eighth day of October 1999

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MODIFIED CARDIOVASCULAR DEVICE

Field of the Invention

The invention relates to a device that may be implanted inside the cardiovascular system so that properties of the body environment may be monitored and a blood flow passage can be enlarged. The device is electrically powered and controlled by an external source of electromagnetic radiation.

Background to the Invention

There is a well known art of devices in the form of cylindrical shape as a wire cage called stents. These stent devices have been developed to enable cardiovascular surgeons and cardiologists to introduce these as part of their treatment to aid healing or relieve an obstruction. The stents are usually initially provided in a collapsed form on an inflatable support. In this form they are introduced into an appropriate blood vessel, such as the femoral artery near the groin, and carefully moved to the site of restricted blood flow. The supporting balloon is then inflated so deforming the stent spring structure to press outwards into the wall of the blood vessel. The implanting apparatus and the inflatable support is then withdrawn, leaving the expanded stent to maintain the blood vessel open and allow improved blood flow.

Another area of surgical implants is the implantation of monitoring and/or stimulating devices. These devices usually have an implanted part which includes an aerial, and an external part which transmits the instructions and power to the implanted part.

For example, a monitoring device may measure the activity of the heart in terms of a electrocardiogram and transmit this information to the primary control. In this way, it is possible to continuously monitor the operation of the heart and provide information to assist preventative therapies to be adopted by a person.

An example of a known monitoring and/or stimulating device is described in United States patent no. 5,314,458. The implantable microstimulator system employs a miniature ferrite-cored coil contained within a hermetically sealed housing to receive control signals and operating power from an RF telemetry system. The tiny coil receives the electromagnetic energy which is transmitted from a non-implantable transmitter which generates a code-

modulated carrier. Demodulator circuitry in the implantable microcircuit is employed to extract the control information, while applying the electromagnetic energy to power the electronic circuitry therein and charge a capacitor which will provide the electrical stimulation to the living being. The electrical stimulation is delivered by a stimulating electrode which has a waffle-like configuration whereby a plurality of iridium oxide electrode pads, coupled in parallel, so as to be characterised by a long effective edge distance, transfer the stimulating charge. The electrical components of the microstimulator are contained within a hermetically sealed housing formed of a glass capsule which is electrostatically bonded to a silicon substrate.

Description of the Invention

It has surprisingly been found that a stent and a monitoring device may be combined into a single unit thereby achieving two objectives with one operation. Further, the combined device resembles a standard stent. Therefore the combined device may be implanted into the patient using the same procedure as for a standard stent.

Accordingly, in one preferred form of the invention, a medical appliance is provided which comprises a spring-based stent incorporating a monitoring device wherein the spring of the stent acts as the aerial for the monitoring device.

Preferably, the monitoring device is located in the support of the stent. Preferably, the monitoring device works in conjunction with a primary control. The monitoring device will preferably include means to monitor predetermined conditions in the vicinity the medical appliance and means to emit signals representative of one or more of these conditions to be received by the primary control.

Preferably, the primary control is separate and located outside the body in which the stent is implanted. Preferably, the primary control communicates with the aerial and is adapted to emit high frequency electromagnetic radiation between 0.5 to 5 GHz. This is particularly useful for deep implants. Preferably, the primary control is a power source for the monitoring device.

In situations where it is difficult to communicate directly with the medical appliance, a second intermediate implant may be necessary which is closer to the skin surface and

which can relay the power and instructions from the primary control device to the medical appliance.

Detailed Description of the Invention

The following is a detailed description of an embodiment of the invention. In this arrangement the wire spring structure of the stent performs the basic function of expanding blood vessels, and can also conduct electrical signals and thereby act as the antenna for receiving electromagnetic energy. The small diameter of blood vessels and the reduction in wavelength caused by the high permittivity of blood and blood vessel wall, requires that the frequency of the electromagnetic radiation be greater than 500 MHz. It has been surprisingly found that electromagnetic radiation up to a frequency of 1700 MHz can be usefully transmitted to an antenna that is implanted inside a blood vessel and immersed in blood. The high frequency electromagnetic radiation causes a typical oscillating current in the wire of the stent and this current may be modified by designing the inductance and capacitance of the wire structure to induce resonance. The resulting current is rectified and used to power the monitoring device.

The direct current is then used to charge either a capacitor or miniature battery. Typically, the circuit would be a low power microprocessor with both A/D ("analogue/digital") inputs and output drivers suitable for generating the pulse train to be applied to the antenna for transmission out of the body. For simple versions of the technology the function of the microprocessor would be replaced by discrete or partially integrated circuits that perform the function of processing the signals from the sensor, analysing the signal then transmitting the alarm signal.

In this arrangement, the electronics are typically used to monitor the electrocardiogram but may also monitor pH, blood flow , pCa and other metabolites. The device also has provision to transmit signals out of the body, typically to give an alarm for an abnormal condition.

At the present time, the stent is best configured as stiff hoops to expand blood vessels but the surgical procedure requires that they be implanted in a collapsed form. Each hoop is pleated with the pleats roughly sinusoidal so that the amplitude of the sinusoid is normal to the plane of the hoop so making the sinusoidal in the same cylindrical plane as the wall of

the blood vessel in which is implanted. The pleating is controlled in amplitude and number of pleats to give a radiation impedance for the antenna similar to the space impedance of the body environment. Similarly, the pleating also gives some control over the inductance and capacitance of the antenna considered as a resonant tank circuit together with the characteristics of the rectifier. The unique combination of all these variable parameters permits the design and fabrication of useful devices that satisfy both the original stent requirements and the efficient reception of electromagnetic power.

Example

The invention will now be further explained and illustrated by the following non-limiting example.

Surgical stainless steel wire 316LVM and diameter 0.0059 in. was pleated with a sinusoid of amplitude 0.039 in. giving five cycles in 0.83 in. This planar structure was then bent to form a hoop and attached to a Schotky diode and measuring apparatus. The device was implanted in the artery of a bovine liver and irrigated with heparinised blood. The entire assembly was then transferred to a chamber for testing microwave transmitters and irradiated with electromagnetic energy that was varied in frequency between 500 MHz and 2000 MHz and the energy received monitored. This test showed satisfactory energy was received up to a frequency of 1300MHz with several peaks including 850 MHz.

It would be understood that a variety of types of wire are useful including titanium and the platinum group, and the wire may have coatings to reduce loss by conduction through the body electrolyte and improve the acceptance of the device by the body immune system. Similarly, a wide variety of stent configurations are workable and most of these can be formed into useful antennas.

Description of the Drawings

The invention will now be further illustrated with reference to the accompanying drawings in which:

Figure 1 is a side perspective view of a preferred embodiment of the invention.

The medical appliance 10 in Figure 1 has the basic elements of a known stent, that is, a spring 11 which is attached to a support 12. In this case, the support 12 is a structure capable of incorporating the elements of a monitoring device.

Due to the function of the spring 11 as an aerial for the monitoring device which is incorporated into the support 12, the amplitude of the sinusoidal pleats is kept small enough so that there is not a great deal of overlap between the loops of the spring in the stent. This prevents overlap of the electromagnetic fields generated by these individual loops.

The support 12 may therefore be at least substantially encapsulated in a biocompatible material, such as a suitable epoxy or the like. The sensors of the monitoring device may be constructed from a suitable biocompatible conductive material, such as titanium.

The medical appliance 10 in Figure 1 is shown in its expanded form. When the medical appliance 10 is being inserted into place, the spring 11 will be in a collapsed form (not shown) to allow for easier insertion.

It is to be understood by those skilled in the technology that many variations or modifications in details of design or construction may be made without departing from the essence of the present invention. Therefore, the invention should be understood to include all such variations and modifications within its scope.

The word 'comprising' as used in this description does not limit the invention claimed to exclude any variants or additions which are obvious to the person skilled in the art and which do not have a material effect upon the invention.

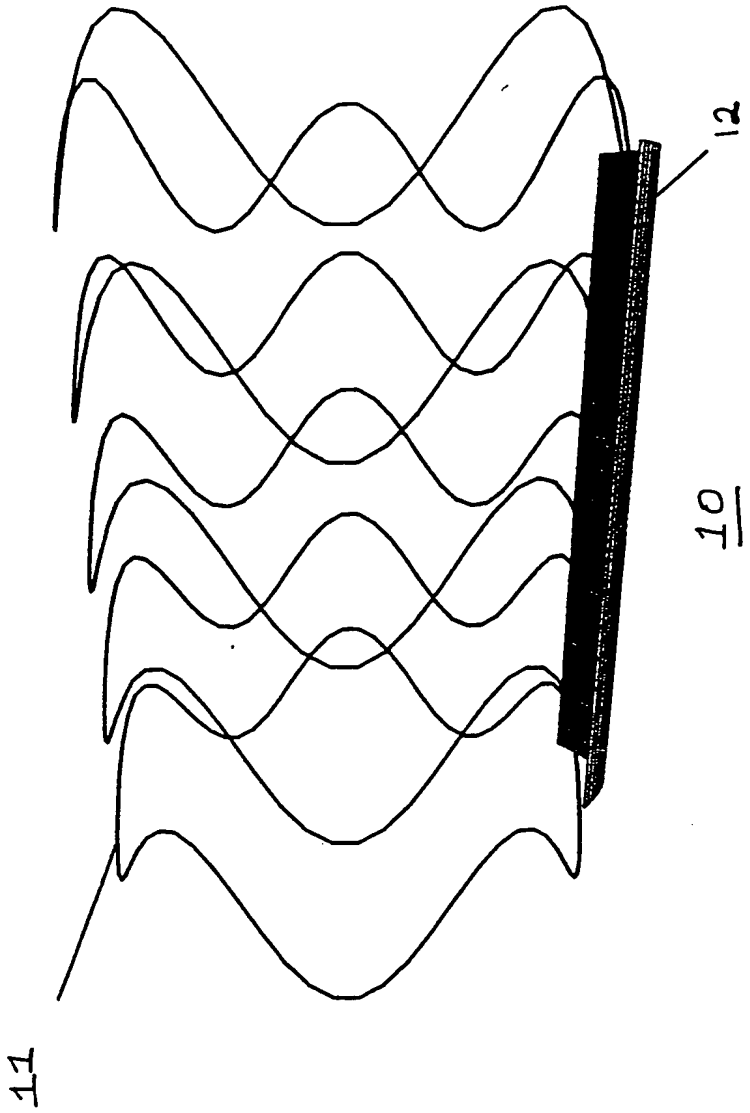

Figure 1